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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,483	07/14/2000	Andrew M. Hoffman	21629-001	6594

7590 02/28/2002

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EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 02/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/616,483	Applicant(s) HOFFMAN, ANDREW M.	
	Examiner Mital B. Patel	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4, 5</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. As set forth by Claim 14, there is an inconsistency between the language in the preamble and certain portion or portions in the body of the claim, thereby making the scope of the claim unclear. The Applicant must clarify what the claim is intended to be drawn to, i.e., either the device alone or the combination of the device and the aerosol container. The Applicant must make the language of the claim consistent with the intent. It should be noted that in considering the claims on the merits, the Examiner has considered the claim(s) as drawn to the combination.

4. There is a lack of antecedent basis for the following limitations:

- Claim 19, line 1, "the size"
- Claim 20, line 1, "the size"

Correction is required.

Claim Rejections - 35 USC § 101

5. Claims 6 and 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The non-statutory subject matter is a mammal. It is improper to positively claim a mammal. The Examiner suggests the following language –the device of claim 1, wherein the device is adapted to be used on a horse, a cow, a sheep, or a goat. Corrections are required with respect to claims 6 and 7.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Foley et al (EP 0537991).

8. **As to claim 1**, Foley teaches a drug delivery device for a mammal comprising a cup-shaped body **38** for enclosing one external nare, wherein the device does not extend into the nostril of the mammal.

9. **As to claim 3**, Foley teaches a device wherein the device does not enclose the mouth of the mammal (See Fig. 14).

10. **As to claim 4**, Foley teaches a device wherein the device comprises a patient-actuated inhalation valve **262**.

11. **As to claim 5**, Foley teaches a device wherein the valve is unidirectional.
12. **As to claim 6**, Foley teaches a device for a horse.
13. **As to claim 7**, Foley teaches a device for a mammal which is a horse.
14. **As to claim 8**, Foley teaches a device wherein the cup-shaped body comprises a flexible interface for contacting the face of the mammal.
15. **As to claim 9**, Foley teaches a device wherein the interface is angled.
16. **As to claim 10**, Foley teaches a device wherein the interface is straight.
17. **As to claim 11**, Foley teaches a device wherein the device comprises a spacer holding chamber **50**, the chamber being in communication with the cup-shaped body.
18. **As to claim 12**, Foley teaches a device wherein the chamber comprises a lumen for receiving a therapeutic agent.
19. **As to claim 13**, Foley teaches a device wherein the lumen is adapted to receive an aerosol container.
20. **As to claim 14**, Foley teaches a device wherein the aerosol container is an MDI.
21. **As to claim 15**, Foley teaches a method for preventing or treating a respiratory condition of a mammal, comprising contacting one nare of the mammal with the device of claim 1 and delivering an effective dose of a therapeutic composition through the device in a single inhaled breath of the mammal. It should be noted the method as recited is inherent in using the device of Foley.
22. **As to claim 16**, Foley teaches a method wherein the mammal is a horse.
23. **As to claim 17**, Foley teaches a method wherein the mammal is a horse.

24. **As to claim 18**, Foley teaches a method wherein the therapeutic composition is administered in the form of a plume of aerosolized particles.

25. **As to claim 21**, Foley teaches a method wherein the therapeutic composition is administered in the form of a dry powder.

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

27. Claims 2, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley et al.

28. **As to claim 2**, Foley teaches essentially all of the limitations except for wherein the device does not enclose a second external nare of the mammal. However, the device would function equally as well with respect to delivering the drug regardless of the device enclosing or not enclosing the second nare. Furthermore, Applicant has not stated how the particular limitation solves a stated problem or is advantageous over the prior art of record. It would also be obvious to one of ordinary skill in the art to modify the device so that it does not enclose the second nare.

29. **As to claims 19 and 20**, Foley fails to specifically teach the limitations with respect to the particle size. However, such a limitation depends on the intended user

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along with the intended therapy and the type of medicament used along. Furthermore, such a limitation may be arrived through routine experimentation and observation.

Conclusion

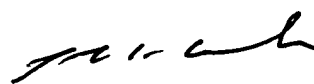
30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5062423, US 4577628, US 4343304, US 4273119, US 3915165 and WO 92/10228.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on 703-308-2702. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp
February 22, 2002


John G. Weiss
Supervisory Patent Examiner
Group 3700